



AP32738 066876.0103  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

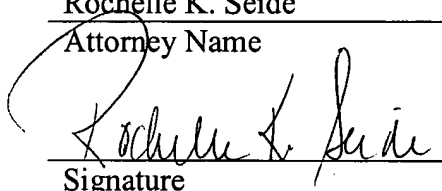
Applicant : Said I.A. SHALABY et al.  
Serial No. : 09/955,877 Examiner : Patten, Patricia A.  
Filed : September 19, 2001 Group Art Unit : 1654  
For : HERBAL COMPOSITIONS AND TREATMENT METHODS

LETTER ENCLOSING COPIES OF IDS DOCUMENTS

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS: Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

May 24, 2004  
Date of Deposit

Rochelle K. Seide  
Attorney Name

  
Signature

32,300  
PTO Registration No.

May 24, 2004  
Date of Signature

Mail Stop: Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

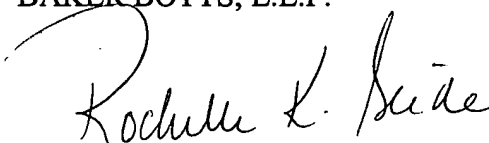
Further to the telephonic interview that Applicant's representatives had with the Examiner on April 14, 2004, Applicants submit herewith copies of the documents cited in the Information Disclosure Statement (IDS) and Form PTO-1449 filed on January 22, 2004. The Examiner indicated that she would mail a Notice of Allowance, but would still consider the documents in Applicants IDS and Form PTO-1449 if copies were expeditiously provided.

Applicants have discovered several minor typographical errors in the IDS and Form PTO-1449 filed on January 22, 2004. Therefore, Applicants have enclosed herewith a marked-up Form PTO-1449 showing the corrections. In addition, to ensure that the cover of any patent issuing from this application correctly cites the documents cited, Applicants have also enclosed a substitute Form PTO-1449 incorporating the corrections. Applicants have further included copies of the January 22, 2004 IDS and Form PTO-1449 for the Examiner's convenience.

While Applicants do not believe any fee is due with this submission, the Commissioner is hereby authorized to deduct any fees required with this submission not otherwise enclosed herewith from Deposit Account No. 02-4377. Two copies of a Fee Transmittal are enclosed.

Respectfully submitted,

BAKER BOTTS, L.L.P.



Rochelle K. Seide  
PTO Reg. No. 32,300

Carmella L. Stephens  
PTO Reg. No. 41,328  
Attorneys for Applicants

Guy F. Birkenmeier  
PTO Reg. No. 52,622  
Agent for Applicants

BAKER BOTTS L.L.P.  
30 Rockefeller Plaza  
New York, NY 10112  
(212) 408-2500

May 24, 2004

Enclosures



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New York, NY 10112  
(212) 408-2500

May 24, 2004

Enclosures

93

BAKER BOTTS LLP

1654  
BPlease type a plus sign (+) inside this box → ☐

# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

|   |                        |                          |
|---|------------------------|--------------------------|
| <b>TRANSMITTAL<br/>FORM</b><br>(to be used for all correspondence after initial filing) | Application Number     | 09/955,877               |
|   | Filing Date            | September 19, 2001       |
|   | First Named Inventor   | Said I.A. SHALABY et al. |
|   | Group Art Unit         | 1654                     |
|   | Examiner Name          | Patten, Patricia A.      |
| Total Number of Pages in This Submission  | Attorney Docket Number | AP32738 066876.0103      |

## ENCLOSURES (check all that apply)

|  |   |   |
|--|---|---|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment / Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application)<br><input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):<br>See attached sheet |
| Remarks <input type="checkbox"/>   |   |   |

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|                         |  |  |
|-------------------------|--|--|
| Firm or Individual name | BakerBotts LLP<br>30 Rockefeller Plaza<br>New York, NY 10112 |  |
| Signature               | <i>Rochelle K. Seide</i>                                     | Att Name: Rochelle K. Seide<br>PTO Reg: 32,300 |
| Date                    | May 24, 2004   |  |

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: May 24, 2004

|                       |                          |      |              |
|-----------------------|--------------------------|------|--------------|
| Typed or printed name | Rochelle K. Seide        |      |              |
| Signature             | <i>Rochelle K. Seide</i> | Date | May 24, 2004 |

Title: HERBAL COMPOSITIONS AND TREATMENT METHODS

Use Space Below for Additional Information:

This submission includes:

- Transmittal (2 pages);
- Fee Transmittal (1 sheet in duplicate);
- Letter Enclosing Copies of IDS Documents (2 pages);
- Substitute Form PTO-1449 (3 pages);
- Marked-up Form PTO-1449 (3 pages);
- Copy of previous Form PTO-1449 (3 pages);
- Copy of previous IDS (4 pages);
- Copies of 27 IDS documents (1 bound volume);
- Return Postcard

**BAKER BOTTS LLP**

# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$)**0****Complete if Known**

|                      |                          |
|----------------------|--------------------------|
| Application Number   | 09/955,877               |
| Filing Date          | September 19, 2001       |
| First Named Inventor | Said I.A. SHALABY et al. |
| Examiner Name        | Patten, Patricia A.      |
| Art Unit             | 1654                     |
| Attorney Docket No.  | AP32738 066876.0103      |

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☐ Deposit Account:Deposit  
Account  
Number  
Deposit  
Account  
Name

02-4377

Baker Botts LLP

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Credit any overpayments☐ Charge any additional fee required under 37CFR 1.16 and 1.17☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity |          | Small Entity |          | Fee Description        | Fee Paid |
|--------------|----------|--------------|----------|------------------------|----------|
| Fee Code     | Fee (\$) | Fee Code     | Fee (\$) |                        |          |
| 1001         | 770      | 2001         | 385      | Utility filing fee     |          |
| 1002         | 340      | 2002         | 170      | Design filing fee      |          |
| 1003         | 530      | 2003         | 265      | Plant filing fee       |          |
| 1004         | 770      | 2004         | 385      | Reissue filing fee     |          |
| 1005         | 160      | 2005         | 80       | Provisional filing fee |          |

**SUBTOTAL (1)** (\$)**0****2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

|                    | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Total Claims       | - 20 = 0     | X              | = 0      |
| Independent Claims | - 3 = 0      | X              | = 0      |
| Multiple Dependent |              |                |          |

| Large Entity |          | Small Entity |          | Fee Description  |
|--------------|----------|--------------|----------|--|
| Fee Code     | Fee (\$) | Fee Code     | Fee (\$) |  |
| 1202         | 18       | 2202         | 9        | Claims in excess of 20                                     |
| 1201         | 86       | 2201         | 43       | Independent claims in excess of 3                          |
| 1203         | 290      | 2203         | 145      | Multiple dependent claim, if not paid                      |
| 1204         | 86       | 2204         | 43       | ** Reissue independent claims over original patent         |
| 1205         | 18       | 2205         | 9        | ** Reissue claims in excess of 20 and over original patent |

**SUBTOTAL (2)** (\$)**0**

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION** (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

| Fee Code | Fee (\$) | Fee Code | Fee (\$) | Fee Description  | Fee Paid |
|----------|----------|----------|----------|--|----------|
| 1051     | 130      | 2051     | 65       | Surcharge - late filing fee or oath  |          |
| 1052     | 50       | 2052     | 25       | Surcharge - late provisional filing fee or cover sheet                     |          |
| 1053     | 130      | 1053     | 130      | Non-English specification  |          |
| 1812     | 2,520    | 1812     | 2,520    | For filing a request for <i>ex parte</i> reexamination                     |          |
| 1804     | 920*     | 1804     | 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805     | 1,840*   | 1805     | 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251     | 110      | 2251     | 55       | Extension for reply within first month                                     |          |
| 1252     | 420      | 2252     | 210      | Extension for reply within second month                                    |          |
| 1253     | 950      | 2253     | 475      | Extension for reply within third month                                     |          |
| 1254     | 1,480    | 2254     | 740      | Extension for reply within fourth month                                    |          |
| 1255     | 2,010    | 2255     | 1,005    | Extension for reply within fifth month                                     |          |
| 1401     | 330      | 2401     | 165      | Notice of Appeal   |          |
| 1402     | 330      | 2402     | 165      | Filing a brief in support of an appeal                                     |          |
| 1403     | 290      | 2403     | 145      | Request for oral hearing   |          |
| 1451     | 1,510    | 1451     | 1,510    | Petition to institute a public use proceeding                              |          |
| 1452     | 110      | 2452     | 55       | Petition to revive - unavoidable   |          |
| 1453     | 1,300    | 2453     | 650      | Petition to revive - unintentional   |          |
| 1501     | 1,330    | 2501     | 665      | Utility issue fee (or reissue)   |          |
| 1502     | 480      | 2502     | 240      | Design issue fee   |          |
| 1503     | 630      | 2503     | 315      | Plant issue fee  |          |
| 1460     | 130      | 1460     | 130      | Petitions to the Commissioner  |          |
| 1807     | 50       | 1807     | 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806     | 180      | 1806     | 180      | Submission of Information Disclosure Stmt                                  |          |
| 8021     | 40       | 8021     | 40       | Recording each patent assignment per property (times number of properties) |          |
| 1809     | 770      | 2809     | 385      | Filing a submission after final rejection (37 CFR 1.129(a))                |          |
| 1810     | 770      | 2810     | 385      | For each additional invention to be examined (37 CFR 1.129(b))             |          |
| 1801     | 770      | 2801     | 385      | Request for Continued Examination (RCE)                                    |          |
| 1802     | 900      | 1802     | 900      | Request for expedited examination of a design application                  |          |

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3)** (\$)**0****SUBMITTED BY**

Name (Print/Type)

Rochelle K. Seide

Registration No.  
(Attorney/Agent)

32,300

(Complete if applicable)

Telephone 212.408.2500

Signature

Rochelle K. Seide

Date

May 24, 2004

Form PTO-1449 U.S. Department of Commerce  
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.  
AP32738 066876.0103

Serial No.  
09/955,877

**INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT**

(Use several sheets if necessary)

Applicant  
Said I.A. SHALABY et al.

Filing Date  
September 19, 2001

Group  
1654

**U.S. PATENT DOCUMENTS**

| *Exam.<br>Init. | Document No.  | Date       | Name           | Class | Subclass | Filing Date<br>if Appropriate |
|-----------------|---------------|------------|----------------|-------|----------|-------------------------------|
|                 | 5 8 7 6 7 2 8 | 03/02/1999 | Kass HD et al. |       |          |                               |
|                 | 5 8 7 4 8 0 4 | 02/23/1999 | Rogers SP      |       |          |                               |
|                 | 5 6 4 8 0 8 9 | 07/15/1997 | Shawkat T      |       |          |                               |
|                 |               |            |                |       |          |                               |
|                 |               |            |                |       |          |                               |

**FOREIGN PATENT DOCUMENT**

| Document No. | Date       | Country     | Class | SubClass | Translator<br>Yes No |
|--------------|------------|-------------|-------|----------|----------------------|
| 7 9 3 9 6 4  | 09/10/1999 | Europe (EP) |       |          |                      |
|              |            |             |       |          |                      |
|              |            |             |       |          |                      |

**OTHER DOCUMENTS (including Author, Title Date, Pertinent Pages, Etc.)**

|  |   |
|--|---|
|  | Harvard School of Public Health Jan 2004, < <a href="http://www.researchmatters.harvard.edu/story.php?article_id=673">http://www.researchmatters.harvard.edu/story.php?article_id=673</a> >   |
|  | Buckwold, Beer, Donis, 2003 "Bovine viral diarrhea as a surrogate model of hepatitis C virus for the evaluation of anti-viral agents" Antiviral Research Vol 60(1):1-15;  |
|  | Cost of Developing a New Drug Increases to About \$1.7 Billion By PETER LANDERS, Wall Street Journal December 8, 2003 < <a href="http://online.wsj.com/article/0,,SB107083909136415400-email,00.html">http://online.wsj.com/article/0,,SB107083909136415400-email,00.html</a> > |
|  | Abramowicz M, ed., "Enfuvirtide (Fuzeon) for HIV Infection" Med Lett Drugs Ther. 2003 Jun 23; 45(1159): 49-50;  |
|  | El-Awady, et al., Clinica Chimica Acta, 283(1-2):1-14 (1999);   |
|  | McHutchison et al., "Interferon Alpha-2b Alone or in Combination with Ribavirin as Initial Treatment for Chronic Hepatitis C", New England Journal of Medicine Vol 339 Number 21 November 19, 1998, 1485-1492;  |

NY02:472768.1

Examiner

Date Considered

\* Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce  
(REV. 2-82) Patent and Trademark Office

Atty. Docket No.  
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Yokozawa, et al., J. Traditional Medicine, 15(1):45-51 (1998)

Alter, M.J., Hepatology, 26(1):62S-65S (1997)

Alam, et al., Phytotherapy Research, 10(1):58-61 (1996);

D.S. Chen, J. Formos. Med. Assoc., 95(1):6-12 (1996);

Detre, et al., Viral Hepatitis Rev., 2:219-228 (1996);

D.C. Dale and D.D. Federman, eds., Sci. Amer. Medicine, New York, 4(8):1-10 (1996);

Hibbs, et al., J. Infect. Dis. 168:789-790 (1993);

Lok, et al., Gastroenterology, 105(6):1833-1838 (1993);

Flint SJ et al., Principles of Virology: Molecular Biology, Pathogenesis, and Control, ASM Press, Washington DC, 1990, p.691;

Medicinal Plants of North Africa, Loutfy Boulos, Reference Publications, Inc., pp.150-51 (1983);

Medicinal Plants of North Africa, pp. 74-75, 92-93 (1983);

Bergmeyer and Horder, Clinica Chemica Acta 105:147f-154f (1980);

Encyclopedia of Common Natural Ingredients, Used in Food, Drugs, and Cosmetics, John Wiley & Sons, New York, p.169 (1980);

International Federation of Clinical Chemistry, Scientific Committee, J. Clin. Chem. Clin. Biochem., 18:521-534 (1980);

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Bergmeyer H. U. Methods of Enzymatic Analysis. Verlag Chemic, (1978), pp. 130-135;

Babbar, et al., Ind. J. Exp. Biol., 8:304-312 (1970);

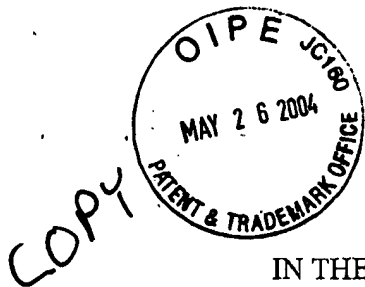
Linus Pauling, General Chemistry, New York, Dover Publications, Inc., 1970, p 744.

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January 22, 2004

Date of Deposit

Carmella L. Stephens

Attorney Name

41,328

PTO Registration No.

*Carmella L. Stephens*  
Signature

January 22, 2004

Date of Signature

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 C.F.R. §1.56, Applicant respectfully requests that the documents relating to the above-identified application listed herein in reverse chronological alphabetical order be considered and made of record in the U.S. Patent and Trademark Office.

1. Harvard School of Public Health Jan 2004,

<[http://www.researchmatters.harvard.edu/story.php?article\\_id=673](http://www.researchmatters.harvard.edu/story.php?article_id=673)>;

COPY

2. Buckwold, Beer, Donis, 2003 "Bovine viral diarrhea as a surrogate model of hepatitis C virus for the evaluation of anti-viral agents" Antiviral Research Vol 60(1):1-15;
3. Cost of Developing a New Drug Increases to About \$1.7 Billion By PETER LANDERS , Wall Street Journal December 8, 2003  
<<http://online.wsj.com/article/0,,SB107083909136415400-email,00.html>>;
4. Enfuvirtide (Fuzeon) for HIV Infection Med Lett Drugs Ther. 2003 Jun 23; 45(1159): 49-50;
5. Abd El-Baset M et al, EP 0793964 published September 10, 1999;
6. El-Awady, et al., Chem. Clinical Acta, 283(1-2):1-14 (1999);
7. Kass HD et al., U.S. Patent No. 5,876,728 issued March 2, 1999;
8. Rogers SP, U.S. Patent No. 5,874,804 issued February 23, 1999;
9. McHutchison et al Interferon Alpha-2b Alone or in Combination with Ribavirin as Initial Treatment for Chronic Hepatitis C, New England Journal of Medicine Vol 339 Number 21 November 19, 1998, 1485-1492;
10. Yokozbawa, et al., J. Traditional Medicine, 15(4):202-207 (1998);
11. Alter, M.J., Hepatology, 26(1):625-655 (1997);
12. Shawkat T, U.S. Patent No. 5,648,089 issued July 15, 1997;
13. Alam, et al., Phytotherapy Research, 10(1):58-61 (1996);
14. D.S. Chen, J. Formos. Med. Assoc., 95(1):6-12 (1996);
15. Detre, et al., Viral Hepatitis Rev., 2:219-228 (1996);
16. D.C. Dale and D.D. Federman, eds. Medicine Sc. Amer., Inc., New York, 4(8):1-8 (1995);
17. Hipps, et al., Infect. Dis. 168:789-790 (1993);

COPY

18. Lok, et al., Gastroenterology, 105(6):1833-1838 (1993);
19. Fields, Virology 2nd ed, New York, Raven Press, 1990 p691;
20. Medicinal Plants of North Africa, Loutfy Boulos, Reference Publications, Inc., pp.150-51 (1983);
21. Medicinal Plants of North Africa, pp. 74-75 (1983);
22. Bergmeyer and Horder, Clin. Chem. Acta 105:147 f. (1980);
23. Encyclopedia of Common Natural Ingredients, Used in Food, Drugs, and Cosmetics, p.169 (1980);
24. International Federation of Clinical Chemistry, Scientific Committee, J. Clin. Chem. Biochem., 18:521-534 (1980);
25. Bergmeyer H. U. Principles of Enzymatic Analysis. Verlag Chemic, (1978);
26. Babbar, et al., Ind. J. Exp. Biol., 8:304-312 (1970); and
27. Linus Pauling, General Chemistry, New York, Raven Press 1970, p 744.

The referenced citations are listed in the accompanying PTO Form 1449. Copies of the documents will follow as soon as they are available. Identification of the documents listed in the attached PTO Form 1449 is not to be construed as an admission of Applicants or Attorneys for Applicants that such documents are available as "prior art" against the above-identified application.

COPY

Applicants enclose herewith the fees required pursuant to 37 C.F.R. §§ 1.17(p) and 1.97(c)(2). Applicants do not believe any additional fee is due with this submission. Nevertheless, the Commissioner is hereby authorized to deduct any fees required with this submission not otherwise enclosed herewith from Deposit Account No. 02-4377. Two copies of this paper are enclosed.

Respectfully submitted,

BAKER BOTTS, L.L.P.

January 22, 2004

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